

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:	Khosravi
Application No.:	09/427260
Filed:	October 25, 1999
For:	Stretchable Anti-Buckling Coiled-Sheet Stent
Examiner:	Brian E. Pellegrino
Group Art Unit:	3738

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2-13525-US01

AMEDNDED APPEAL BRIEF

This is an Amended Appeal Brief for the above-identified application in response to the Notice of Non-Compliant Appeal Brief mailed April 2, 2009. The error noted in the summary of claimed subject matter section of the brief has been corrected. A Notice of Appeal was filed in this case on February 2, 2009. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

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(C) Real Party in Interest

The Application is assigned to Boston Scientific Cupertino Corp, formerly known as EndoTex Interventional Systems, Inc., 10231 Bubb Rd, Cupertino, California 95014-4167, a Delaware Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(D) Related Appeals and Interferences

At present there are no related appeals or interferences.

(E) Status of Claims

In the Final Office Action of November 14, 2008, claims 29, 30, 55, 56, 59, 60, and 62-64 were finally rejected and are the subject of this appeal.

Claims 1-28, 31-54, 57-58, 61 and 65-66 have been canceled.

(F) Status of Amendments

Subsequent to the Final Office Action of November 14, 2008, Applicant filed an Amendment After Final and request for reconsideration on January 7, 2009 in which a drawing which was omitted from the previous Amendment was submitted.

In the Advisory Action of January 16, 2009, the Examiner indicated that the proposed amendment to the drawing in the Amendment After Final of January 7, 2009 and the proposed Amendment to the Specification in the Amendment of August 12, 2008 would not be entered because the Examiner asserted that it was new matter. This is discussed in greater detail in the Summary of Claimed Subject Matter.

(G) Summary of Claimed Subject Matter

A summary of representative claims and a non-limiting listing of locations where support may be found [bracketed citations] and reference numerals is provided as follows:

Independent claim 29 recites a stretchable stent, comprising a coiled-up sheet, a plurality of locking elements, a plurality of first cells, a plurality of peripheral connector elements (736) and a plurality of second cells [pg. 4, line 13 to pg. 5, line 2; Fig. 9 and 10A as filed]. The coiled-up sheet has overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof [pg. 14, lines 14-18]. The coiled-up sheet is expandable between a contracted condition and one or more enlarged conditions [pg. 5, lines 3-19]. The coiled-up sheet defines a periphery in a plane substantially perpendicular to a longitudinal axis thereof [Figs. 1B and 9].

The plurality of locking elements extend from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions [pg. 6, lines 5-9; pg. 18, line 19 to pg. 19, line 4].

Each first cell is defined by a stretchable element (730) formed in the coiled-up sheet and has a first area [pg. 28, line 6 to pg. 29, line 8; Figs. 9 and 10A]. The stretchable elements (730) have a shape memory such that the stretchable elements (730) are plastically deformable towards an unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above body temperature [pg. 14, lines 3-13; pg. 15, lines 3-12].

Each stretchable element (730) comprises a pair of peripherally expandable wing-like elements (738) extending generally parallel to the longitudinal axis [pg. 28, line 6 to pg. 29, line 8; Fig. 9 and 10A]. Each pair of peripherally expandable wing-like elements (738) comprises a first longitudinal element (740) and a second longitudinal element (742) [pg. 28, line 6 to pg. 29, line 8; Fig. 9 and 10A]. Each longitudinal element (740, 742) is curvilinear and has three turns between a first end and a second end of the longitudinal element (740, 742) [pg. 28, line 6 to pg. 29, line 8; Fig. 9 and 10A]. The first end is engaged to a peripheral connector element (736) and the second end is engaged to a looped end (744) [pg. 28, line 6 to pg. 29, line

8; Fig. 9 and 10A]. The looped end (744) engages the first and second longitudinal elements (740, 742) [pg. 28, line 6 to pg. 29, line 8; Fig. 9 and 10A].

Each second cell is defined by four longitudinal elements (740, 742) and two peripheral connector elements (736). Each of the four longitudinal elements (740, 742) form a portion of a different stretchable element (730). Each second cell has a second area, the second area being greater than the first area when the stent is in the unstretched condition [Fig. 9].

Independent Claim 55 recites a stretchable stent, comprising a coiled-up sheet and a plurality of stretchable cells (730) [pg. 4, line 13 to pg. 5, line 2; Fig. 9 and 10A]. The coiled-up sheet has overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, and defining a periphery [pg. 14, lines 14-18]. The coiled-up sheet is unrollable between a contracted condition and one or more enlarged conditions [pg. 5, lines 3-19].

The plurality of stretchable cells (730) is formed in the coiled-up sheet, each stretchable cell (730) defines a first cell [pg. 28, line 6 to pg. 29, line 8; Fig. 9]. The first cell has a first size when the stent is in the contracted condition [Fig. 9]. Each stretchable cell (730) is defined by a pair of peripherally expandable wing-like elements (738) extending generally parallel to the longitudinal axis [pg. 28, line 6 to pg. 29, line 8; Fig. 9]. Each wing-like elements (738) comprises first and second members (740, 742) that are curvilinear and have three turns between a looped end (744) thereof [pg. 28, line 6 to pg. 29, line 8; Fig. 9]. The wing-like elements (738) are expandable about the periphery between an unstretched condition to facilitate placement in a delivery device in the contracted condition and a stretched condition to facilitate expansion of the coiled-up sheet to the one or more enlarged conditions upon deployment from the delivery device [pg. 14, lines 3-13; pg. 15, lines 3-12].

Circumferentially adjacent stretchable cells (730) are engaged by a peripheral connector element (736) and longitudinally adjacent stretchable cells (730) are engaged at their looped ends (744), thereby forming a plurality of quartets of stretchable cells [pg. 28, line 6 to pg. 29, line 8; Fig. 9]. A plurality of second cells wherein each second cell is defined by two peripheral connector elements (736) and four curvilinear members (740, 742), one curvilinear member (740, 742) from each stretchable cell (730) forming one quartet of the plurality of

quartets of stretchable cells [pg. 28, line 6 to pg. 29, line 8; Fig. 9]. The second cell has a second size when the stent is in the contracted condition, the second size being larger than the first size [Fig. 9].

Independent claim 59 recites an expandable stent having an unexpanded state and an expanded state [pg. 5, lines 3-19]. The stent comprises a coiled-up sheet, a plurality of stretchable elements (730), and a plurality of second cells [pg. 4, line 13 to pg. 5, line 2; Fig. 9 and 10A as filed].

The coiled-up sheet has overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof [pg. 14, lines 14-18]. The coiled-up sheet is expandable between a contracted condition and one or more enlarged conditions [pg. 5, lines 3-19]. The coiled-up sheet defines a periphery in a plane substantially perpendicular to a longitudinal axis thereof [Figs. 1B and 9].

The plurality of stretchable elements (730) is formed in the coiled-up sheet [pg. 28, line 6 to pg. 29, line 8; Fig. 9]. The plurality of stretchable elements (730) defines a plurality of first cells [Fig. 9]. Each of the plurality of first cells has a first area when the stent is in an unstretched condition [Figs. 9 and 10A]. Each stretchable element (730) comprises a pair of peripherally expandable wing-like elements (738) extending generally parallel to the longitudinal axis [pg. 28, line 6 to pg. 29, line 8; Fig. 9 and 10A]. Each of said wing-like elements (738) comprises first and second members (740,742) that are curvilinear and have three turns and are connected to a longitudinally adjacent wing-like element (740,742) at a looped end (744) thereof [pg. 28, line 6 to pg. 29, line 8; Fig. 9 and 10A]. The stretchable elements (730) have a shape memory such that the stretchable elements (730) are plastically deformable towards the unstretched condition at a first temperature, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above a second temperature [pg. 14, lines 3-13; pg. 15, lines 3-12].

Each second cell is defined by four longitudinal elements (740,742) [Fig. 9]. Each longitudinal element (740,742) that defines the second cell forms a portion of a different stretchable element (730) [Fig. 9]. Each of the plurality of second cells has a second area when the stent is in the unstretched condition, the second area being greater than the first area [Fig. 9].

Applicants have included an annotated copy of FIG. 9 below wherein a first cell as well as a second cell is labeled. The annotations further include a guide box that has been drawn around four first cells for convenience in identifying the structures. No changes or modifications to the originally depicted stent design have been made. It should be noted that in the Advisory Action of January 16, 2009, a similarly annotated version of FIG. 9 was considered “new matter” by the Examiner, though no actual rejection under 35 USC or 37 CFR was articulated. Applicants assert that the annotations merely identify the claimed structures that are present in FIG. 9 as filed with lead lines and text, as well as the aforementioned guide box, and cannot be considered new matter. Should the Board refuse to consider this issue or the annotated image, Applicants have also included a non-annotated (original) copy of FIG. 9 as filed on the following page.

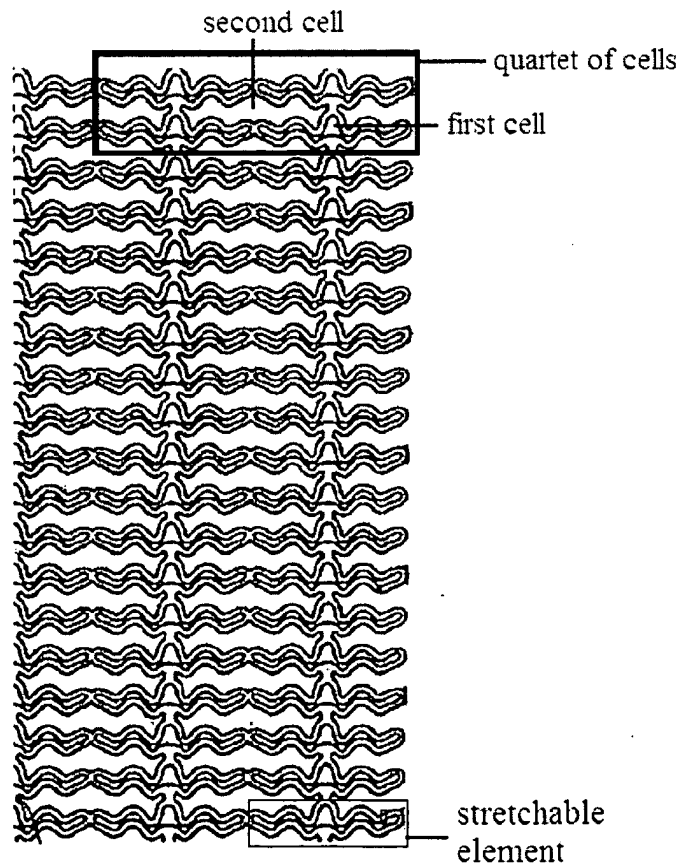


FIG. 9 as filed:

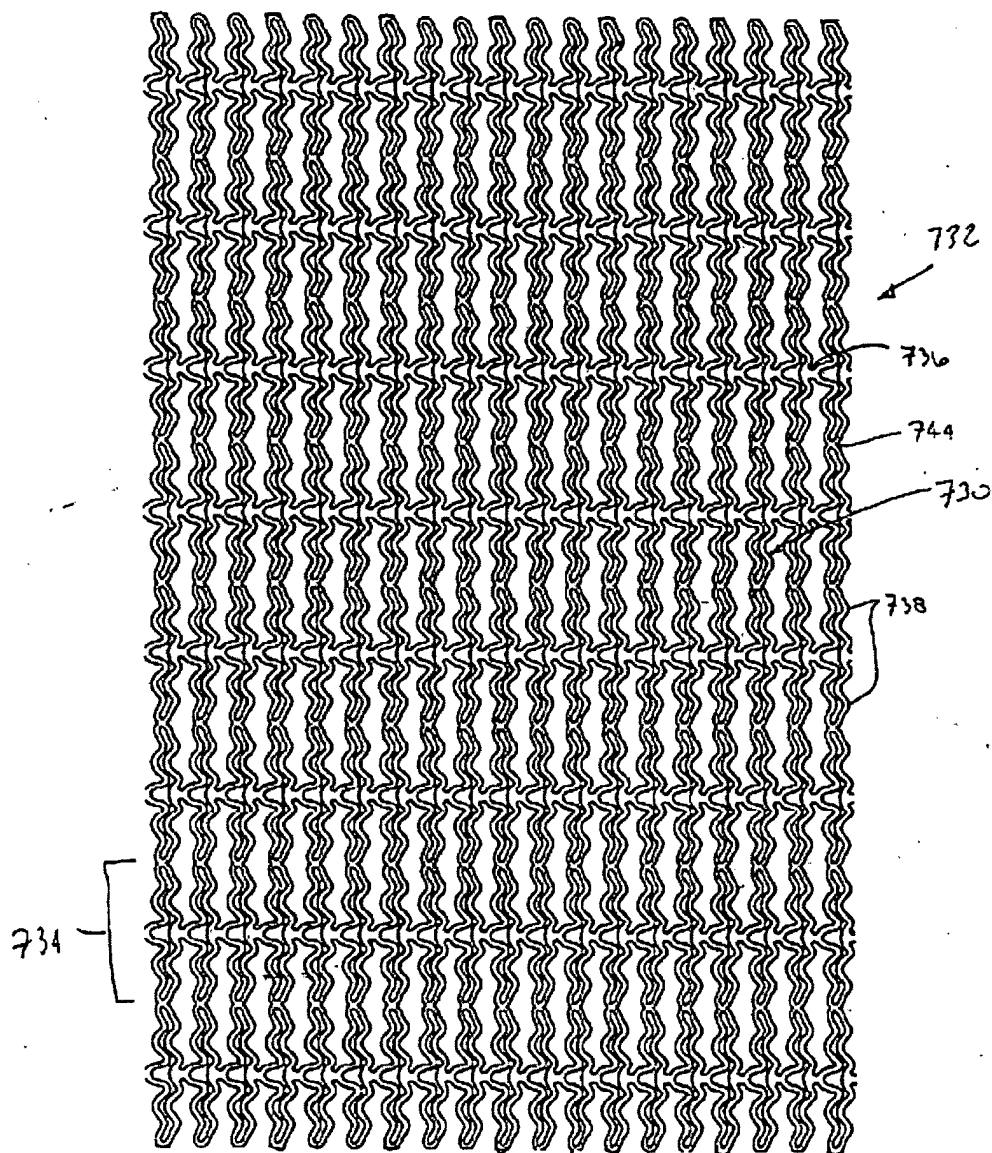
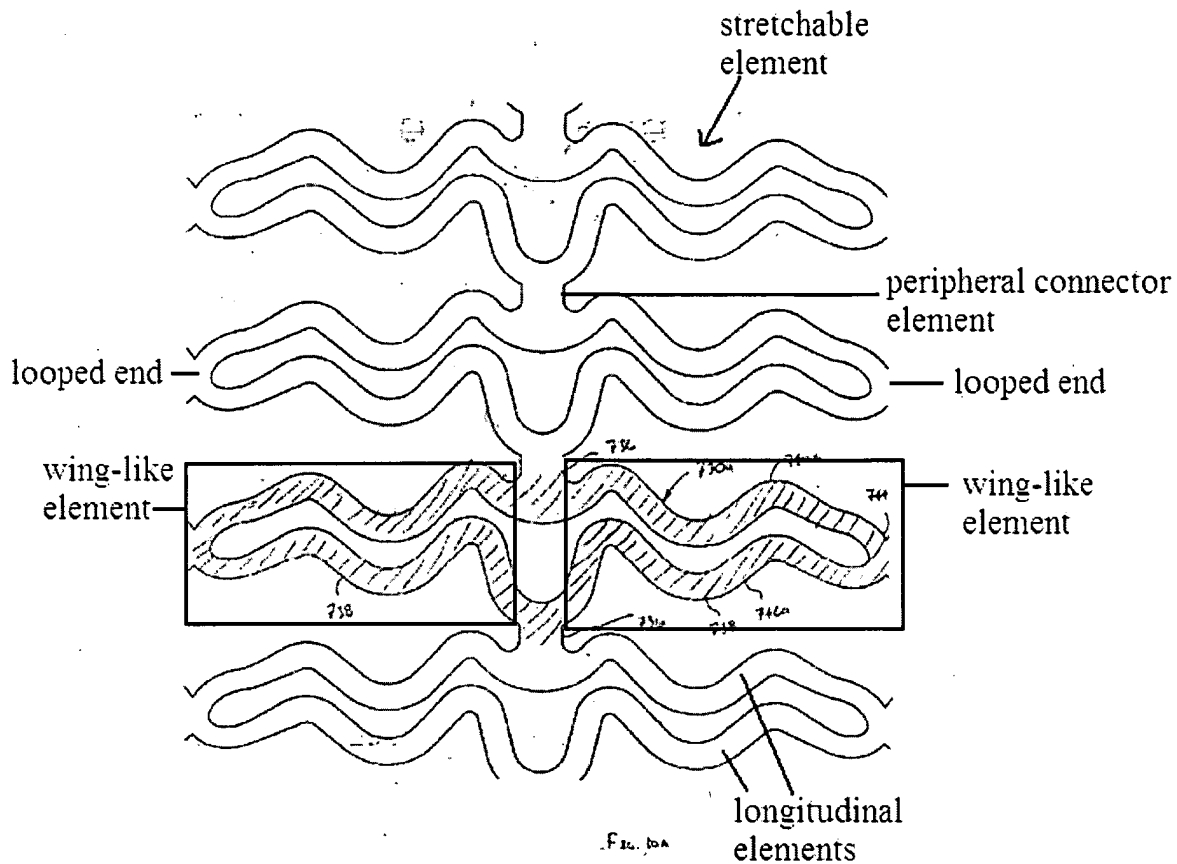


FIG. 9

Applicants have also provided an annotated copy of Fig. 10A of the application as filed:



(H) Grounds of Rejection to be Reviewed on Appeal

1. Whether the Examiner erred in rejecting claims 29, 30, 55, 56, 59, 60, and 62-64 under 35 U.S.C. §103(a) as being unpatentable over U.S. 2001/00472000 to White et al. in view of U.S. 5,824,054 to Khosravi et al.

(I) Argument

1. The Examiner erred in rejecting claims 29, 30, 55, 56, 59, 60, and 62-64 under 35 U.S.C. §103(a) as being unpatentable over U.S. 2001/00472000 to White et al. in view of U.S. 5,824,054 to Khosravi et al.

The Examiner asserted that White discloses a stent comprising a plurality of stretchable elements as recited but does not disclose that the stent is formed of a coiled sheet or include locking elements. The Examiner further asserted that Khosravi shows a sheet stent having a plurality of locking elements as with locking elements as recited.

Applicants disagree that the combination of White and Khosravi render the instant claims obvious.

Fig. 15 of White does not teach "three turns" as recited in the instant claims so Examiner looks to Fig. 10 of White

The Examiner asserted that "Figs. 15A,B show a stent formed of a plurality of stretchable elements defining a plurality of cells 22." For reference, Applicants have provided a copy of a portion of Fig. 15B of White which shows the stent in a compressed state (White [paragraph [0030]]):

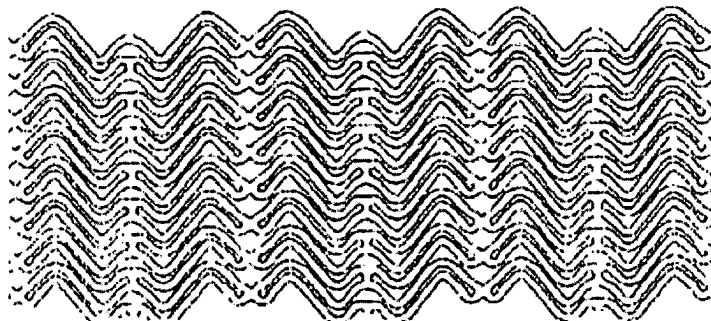


FIG. 15B

As can be seen above, Fig. 15B does not teach “each longitudinal element being curvilinear and having three turns between a first end and a second end of the longitudinal element” as recited in independent claim 29; “first and second members that are curvilinear and have three turns between a looped end thereof” as recited in independent claim 55; or “each of said wing-like elements comprising first and second members that are curvilinear and have three turns” as recited in independent claim 59.

Thus, the Examiner further asserted that “White also shows (Fig. 10) the stents can have cells such that they have longitudinal elements that are curvilinear and have three turns between ends.” For reference, Applicants have provided a copy of Fig. 10 of White:

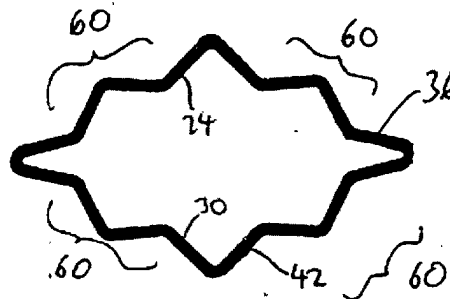


Fig. 10

White states that “Fig. 10 is an enlarged side elevational view of a cell of portion of a stent according to another embodiment of the present invention” (paragraph [0027], emphasis added). White further states that “FIG. 10 illustrates a cell 22 where each strut 24, 30, 36 and 42 has a compensating portion 60” (paragraph [0040]).

Applicants note that **none** of Figs. 1-18 of White show a stent design comprised of a plurality of cells having the configuration shown in Fig. 10 of White. Thus, the configuration of Examiner’s stent is theoretical.

A Drawing of Examiner's Theoretical Stent in White is Required to Support Examiner's Assertion that White Discloses First and Second Cells as Recited in the Instant Claims

Without a drawing in White illustrating this "theoretical stent," Applicants submit that no objective evidence supports the Examiner's assertions that White teaches a stent as recited in the instant claims. The instant claims recite in part:

a plurality of first cells, each first cell being defined by a stretchable element ... having a first area ... and a plurality of second cells, each second cell being defined by four longitudinal elements and two peripheral connector elements ... each second cell having a second area, the second area being greater than the first area when the stent is in the unstretched condition
(claim 29)

a plurality of stretchable cells ... each stretchable cell defining a first cell, the first cell having a first size when the stent is in the contracted condition ... a plurality of second cells wherein each second cell is defined by two peripheral connector elements and four curvilinear members ... the second cell having a second size when the stent is in the contracted condition, the second size being larger than the first size.
(claim 55)

a plurality of stretchable elements ... defining a plurality of first cells, each of the plurality of first cells having a first area when the stent is in an unstretched condition ... a plurality of second cells, each second cell being defined by four longitudinal elements ... each of the plurality of second cells having a second area when the stent is in the unstretched condition, the second area being greater than the first area
(claim 59)

As can be seen above, the first cells of the instant claims are defined either by a stretchable element or a stretchable cell. Thus, the area/size of the first cell depends upon the configuration of the stretchable element/cell. The second cells of the instant claims are respectively defined by four longitudinal elements and two peripheral connector elements, two peripheral connector elements and four curvilinear members, or four longitudinal elements. Thus, the area/size of the second cell depends upon the configuration of the elements or the elements and members that define the second cell.

Fig. 10 of White only shows one cell. Therefore, Fig. 10 cannot disclose first and second cells as recited in the instant claims. Furthermore, as discussed above, White does not show a stent comprising a plurality of cells having the configuration shown in Fig. 10. Therefore, White cannot disclose first and second cells as recited in the instant claims because the configuration of the elements of the stent affect the size/area of the cells of the stent and the configuration of the elements of the theoretical stent is unknown since White does not provide a figure.

The Cell of Fig. 10 of White is in an Expanded Condition – There is No Objective Evidence as to the Configuration of the Cell shown in Fig. 10 in an Unstretched/Contracted Condition

The instant independent claims recite in part (emphasis added):

Claim 29: each second cell having a second area, the second area being greater than the first area *when the stent is in the unstretched condition*

Claim 55: the first cell having a first size *when the stent is in the contracted condition* ... the second cell having a second size *when the stent is in the contracted condition*, the second size being larger than the first size

Claim 59: each of the plurality of first cells having a first area *when the stent is in an unstretched condition* ... each of the plurality of second cells having a second area *when the stent is in the unstretched condition*, the second area being greater than the first area

Although Fig. 10 of White is not described as being either in an expanded state or an unexpanded state, Applicants submit that an inference that the cell shown in Fig. 10 is in an expanded state can be drawn from White as a whole. For example, Fig. 3A of White, positioned above on the same drawing sheet, is described as being in an expanded state (see paragraphs [0027], [0035], [0040] and Figs. 2A and 2B of White). For comparison, Applicants have provided copies of Fig. 3A and Fig. 10 of White:

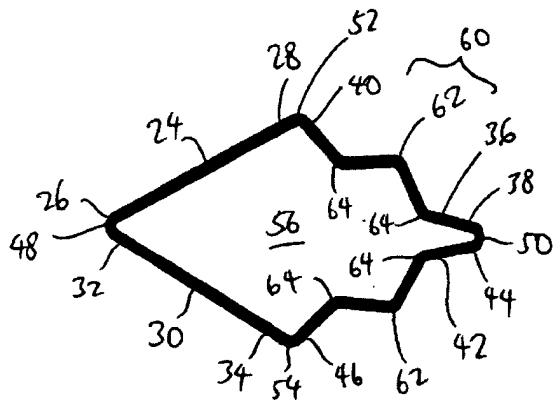


Fig. 3A

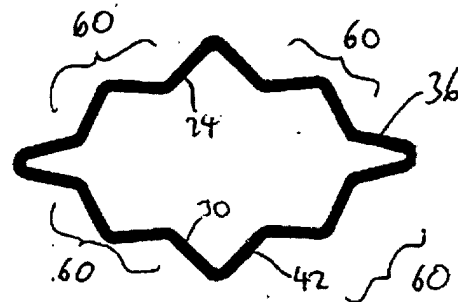


Fig. 10

Therefore, Applicants submit that the cell shown in Fig. 10 of White is in an expanded state. White does not show the cell in Fig. 10 in an unstretched/contracted condition. As discussed above, the configuration of the stent in the unstretched/contracted condition affects the area(s) of the first and second cells. Therefore, the Examiner lacks any objective evidence about the configuration of the individual cell shown in Fig. 10 in an unstretched/contracted condition. The Examiner also lacks any objective evidence about the configuration of a theoretical stent comprising a plurality of such cells.

The Examiner's Reliance of Figs. 6A, 7, 8, 9 and 15B is Misplaced Because Those Figures Do Not Show a Stretchable Cell or Stretchable Element as Recited in the Instant Claims

The Examiner asserted that "to further support that White does show cells in a stent pattern with different areas or size in adjacent section, see Figs. 6A,7,8,9,15B."

Even if Examiner's assertion is correct, Applicants submit that it has no bearing on the instant claims because none of Figs. 6A, 7, 8, 9, or 15B of White show a stretchable cell or stretchable element as recited in the instant claims. As discussed above, the configuration of the struts/members defining the first and second cells affects the areas/sizes of the first and second cells. Because the configuration of the struts/members defining the cells in Figs. 6A, 7, 8, 9, and 15B are different than the configuration of the struts/members as recited in the instant

claims, Applicants submit that these figures cannot be used support an assertion that White discloses first and second cells as recited in the instant claims.

Furthermore, Applicants note that Figs. 6A, 7, 8, and 9 of White are not in a compressed state. Applicants submit that this is further evidence that these figures cannot be used to support an assertion that White discloses first and second cells as recited in the instant claims. Applicants also note that although Fig. 15B of White is in a compressed state, as discussed above, Fig. 15B does not show three turns as recited in the instant claims. Therefore, Applicants submit that Fig. 15B of White also cannot be used to support an assertion that White discloses first and second cells as recited in the instant claims.

For at least these reasons, Applicants submit that Examiner's reliance on these figures is misplaced.

The Addition of a Coiled Sheet with Locking Elements Asserted to be Disclosed by Khosravi Does not Address the Failure of White to Teach Each and Every Element of the Instant Claims

Based on the above, Applicants submit that White does not teach each and every element of the instant claims. The addition of Khosravi which the Examiner asserts discloses a sheet stent having a plurality of locking elements does nothing to address the failure of White to teach each and every element of the instant claims. For at least these reasons, Applicants submit that the combination of White and Khosravi does not render claims 29-30, 55-56, 59-60 and 62-64 obvious. Applicants request reversal of the rejection.

CONCLUSION

The instant claims are patentably distinct over White in view of Khosravi.
Consequently reversal of the rejection is respectfully requested.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS, P.A.

Date: April 8, 2009

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(J) Claims Appendix

29. A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions, the coiled-up sheet defining a periphery in a plane substantially perpendicular to a longitudinal axis thereof;

a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions; and

a plurality of first cells, each first cell being defined by a stretchable element formed in the coiled-up sheet and having a first area, the stretchable elements having a shape memory such that the stretchable elements are plastically deformable towards an unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above body temperature;

wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each pair of peripherally expandable wing-like elements comprising a first longitudinal element and a second longitudinal element, each longitudinal element being curvilinear and having three turns between a first end and a second end of the longitudinal element, the first end being engaged to a peripheral connector element and the second end being engaged to a looped end, the looped end engaging the first and second longitudinal elements;

a plurality of peripheral connector elements; and

a plurality of second cells, each second cell being defined by four longitudinal elements and two peripheral connector elements, each of the four longitudinal elements forming a portion of a different stretchable element, each second cell having a second area, the second area being greater than the first area when the stent is in the unstretched condition.

30. The stretchable stent of claim 29, wherein circumferentially adjacent stretchable

elements being connected at a point intermediate the pair of wing-like elements by a peripheral connector element.

55. A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, and defining a periphery, the coiled-up sheet being unrollable between a contracted condition and one or more enlarged conditions; and

a plurality of stretchable cells formed in the coiled-up sheet, each stretchable cell defining a first cell, the first cell having a first size when the stent is in the contracted condition, each stretchable cell being defined by a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each of said wing-like elements comprising first and second members that are curvilinear and have three turns between a looped end thereof, the wing-like elements being expandable about the periphery between an unstretched condition to facilitate placement in a delivery device in the contracted condition and a stretched condition to facilitate expansion of the coiled-up sheet to the one or more enlarged conditions upon deployment from the delivery device;

circumferentially adjacent stretchable cells being engaged by a peripheral connector element and longitudinally adjacent stretchable cells being engaged at their looped ends thereby forming a plurality of quartets of stretchable cells, a plurality of second cells wherein each second cell is defined by two peripheral connector elements and four curvilinear members, one curvilinear member from each stretchable cell forming one quartet of the plurality of quartets of stretchable cells, the second cell having a second size when the stent is in the contracted condition, the second size being larger than the first size.

56. The stretchable stent of claim 55, further comprising a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions.

59. An expandable stent, the expandable stent having an unexpanded state and an expanded state, the stent comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions, the coiled-up sheet defining a periphery in a plane substantially perpendicular to a longitudinal axis thereof; and

a plurality of stretchable elements formed in the coiled-up sheet, the plurality of stretchable elements defining a plurality of first cells, each of the plurality of first cells having a first area when the stent is in an unstretched condition, wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each of said wing-like elements comprising first and second members that are curvilinear and have three turns and being connected to a longitudinally adjacent wing-like element at a looped end thereof, and wherein the stretchable elements have a shape memory such that the stretchable elements are plastically deformable towards the unstretched condition at a first temperature, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above a second temperature;

a plurality of second cells, each second cell being defined by four longitudinal elements, each longitudinal element defining the second cell forming a portion of a different stretchable element, each of the plurality of second cells having a second area when the stent is in the unstretched condition, the second area being greater than the first area.

60. The expandable stent of claim 59, further comprising:

a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions.

62. The expandable stent of claim 59, wherein said first temperature is at or below about 25 degrees Celsius, and said second temperature is body temperature.

63. The stretchable stent of claim 29, wherein the turns of the first longitudinal element and the turns of the second longitudinal element are circumferentially aligned.

64. The stretchable stent of claim 29, each longitudinal element being curvilinear and having three turns between the first end and the second end of the longitudinal element when the stent is in the contracted condition and when the stent is in an enlarged condition.

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(K) Evidence Appendix - None

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(L) Related Proceedings Appendix - None